The Office Action mailed September 19, 2002 (Paper No. 11), however, beginning with items numbered 13 and 14 of the action, and "upon further consideration", now requires restriction, under 35 USC 121, among the 22 claims pending in this application, as follows:

I. Claims 1-14, characterized as drawn to an immunologically active component and a single component vaccine, classified in class 424, subclasses 130.1 and 269.1.
II. Claims 15-17, characterized as drawn to a multi component vaccine, classified in class 424, subclass 183.1.
III. Claims 18-22, characterized as drawn to a method of preventing disease, classified in class 534, subclass 7.22.

Item 13, on page 4 of the Office Action, continues to explain that the inventions are distinct each from the other for the following reasons:
- Groups I-II are drawn to structurally and functionally different products.
- The inventions are shown to be distinct because they are drawn to distinct products, made by different methods and they are physically and functionally distinct molecules.

Item 13 further states that Inventions I and III are related as product and process of use; and that the inventions can be shown to be distinct if either or both of the following can be shown:
(1) the process for using the product as claimed can be practiced with another materially different product, or,
(2) the product as claimed can be used in a materially different process of using that product (citing MPEP ¶ 806.05(h)), and in the instant case antiparasitic agents can be used to treat or prevent EPM.

The Office Action in item 14, additionally requires election, among newly categorized distinct species identified within each of Groups I, II and III, depending on which Group is elected to apparently 7+ of such newly categorized species in Group I, apparently 2+ of such newly categorized species in Group II, and apparently 9+ of such newly categorized species in Group III.

Still further, the Office Action requires election to a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is held to be allowable, the Office Action further noting that currently, claims 1, 15 and 18 are generic.

Initially, it must be noted that the restriction requirement is not capable of being understood in that invention I is said to be classified in class 424, subclasses 130.1 and 269.1. Subclass 130.1, however, is defined in the Manual of Classification as,

IMMUNOGLOBULIN, ANTISERUM, ANTIBODY, OR ANTIBODY FRAGMENT, EXCEPT CONJUGATE OR COMPLEX OF THE SAME WITH NONIMMUNOGLOBULIN MATERIAL

NONE of the components, species, etc. of claims 1-14, the claims said to comprise Group I, are comprised within this definition, since none of the claimed components, species, etc. fit within the definition of IMMUNOGLOBULIN, ANTISERUM, ANTIBODY, OR ANTIBODY FRAGMENT. Therefore the restriction requirement is in error.

Similarly, the Office Action has categorized the invention of claims 15-17, Group II, as being classified in 424/183.1, which is an indented subclass of 178.1. Note, however, the definition of subclass 183.1 reads,

Conjugated to proteinaceous toxin or fragment thereof (e.g., conjugated t diphtheria toxin, Pseudomonas exotoxin, ricin, gelonin, abrin, etc.),
And the definition of subclass 178.1, reads,
CONJUGATE OR COMPLEX OF MONOCLONAL OR POLYCLONAL ANTIBODY, IMMUNOGLOBULIN, OR FRAGMENT THEREOF WITH NONIMMUNOGLOBULIN MATERIAL.

NONE of the components, species, etc. of claims 15-17, the claims said to comprise Group II, are comprised within this definition, since none of the claimed components, species, etc. fit within the definition of a conjugate, complex or antibody. Therefore the restriction requirement is further in error in its classification of Group II, and in creating an artificial distinction between Groups I and II.

Similarly, the Office Action has categorized the invention of claims 18-22, Group II, as being classified in class 534, subclass 7.22. However, a search of the USPTO website reveals, first, that class 534 relates to organic compounds, and, second, that there is no subclass identifiable as subclass 7.22.

In short, the restriction requirement as stated is based on incorrect and artificial classifications, is improper and should be withdrawn.

Under 35 U.S.C. 121 "two or more independent and distinct inventions ... in one application may ... be restricted to one of the inventions." Inventions are "`independent'" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "`distinct'" means that "two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, and are patentable over each other" (MPEP 802.01). However,

even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Under Patent Office examining procedures, "If the search and examination of an entire application can be made without serious burden, the Examiner is encouraged to examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988).

In the present instance, the central aspect of all the claims is an immunologically active component vaccine which produces a specific antibody response. It would therefore follow that a search directed to such components would extend to the relevant areas of classification where the use of such compositions would be searched would be searched. In view thereof, Applicants urge that the restriction be withdrawn and that all of the claims of record by examined simultaneously as was already previously done in the Office action comprised in Paper No. 4.

It is obviously useful to have classifications which may well aid and facilitate searching, but the classifications do not categorically support a finding that the invention claimed should therefore be restricted.

Examples abound of granted US patents that contain multiple claim forms and multiple species which have gained separate classifications. To cite just a few examples, see US Patents:

6,197,301 - containing claims to these varieties: a polypeptide, a fusion protein, a vaccine, a method of treating and preventing, a diagnostic kit, a method for detecting. This patent included a field of search (under current classifications) encompassing 5 subclasses of 424; 5 subclasses of 530; 5 subclasses of 435; 1 subclass of 536; and one subclass of each of 436 and 514.

5,871,150 - containing claims to a vaccine composition and a method, including a field of search (under current classifications) encompassing 9 subclasses of classes 424, 435 and 530.

5,871,748 - containing claims to a method of producing active immunity, a vaccine preparation, an article of manufacture, including a field of search (under current classifications) encompassing 7 subclasses of classes 424, 530 and 435.

6,261,569 - containing claims to a synthetic peptide antigen, a method of preparing such an antigen, a method of preparing an immunogenic composition and a method of inducing antibodies, including a field of search (under current classifications) encompassing 18 subclasses of classes 424, 530 and 514, and including specifically, inter alia, 424/184.1, 530/825 and 530/826.

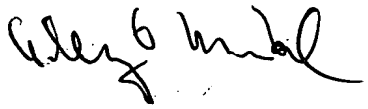
6,030,618 containing claims to a composition, a method of eliciting an immune response, a kit, including a field of search (under current classifications) encompassing 2 subclasses of classes 424, 530 and 514, and including specifically, inter alia, 424/184.1, 530/825 and 530/826.

For the above reasons, Applicants request withdrawal of the Requirement for Restriction, and allowance of all pending claims as all the prior substantive rejections have been withdrawn, traversed or rendered moot. Early action and allowance on the merits as to all of the claims presently pending in the case is therefore submitted to be in order.

While for the reasons stated, the restriction requirement is unsupportable, has been traversed, and should be withdrawn, the Office Action, nevertheless, requires that applicant make an election. Accordingly, election is made to the invention of Group I, and species a) of Group I. Claims 2, 4-8, and 10-14 are readable thereon. Additionally the species elected is also a species of claims 15-17 of Group II, and claims 18-22 of Group III.

No fees are believed to be due for this response. However, should this be in error, authorization is hereby given to charge Deposit account No. 01-1425.

Respectfully submitted,



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